

**Appl. No.** : 10/066,513  
**Filed** : January 30, 2002

### LISTING OF CLAIMS

1. **(Previously presented)** A transmucosally administrable composition comprising:

a pharmaceutically active compound; and

a permeation enhancing agent, wherein said agent is selected from the group consisting of histamine, histamine dihydrochloride, histamine phosphate, a pharmaceutically acceptable salt thereof, and other histamine agonists and wherein said composition comprises about 0.001% to about 25% weight/volume of said permeation enhancing agent, wherein said permeation enhancing agent enhances the transmucosal delivery of said pharmaceutically active compound to a subject.

2. **(Withdrawn)** The transmucosally administrable composition of claim 1 wherein said composition comprises about 0.001% to about 25% weight/volume of said permeation enhancing agent.

3. **(Original)** The transmucosally administrable composition of claim 1, wherein said permeation enhancing agent is histamine dihydrochloride.

4. **(Original)** The transmucosally administrable composition of claim 1, wherein said permeation enhancing agent is histamine phosphate.

5. **(Original)** The transmucosally administrable composition of claim 1, wherein said permeation enhancing agent is histamine.

6. **(Original)** The transmucosally administrable composition of claim 1, wherein said composition comprises about 0.2% to about 90% of said pharmaceutically active compound.

7. **(Original)** The transmucosally administrable composition of claim 1, wherein said composition further comprises about 0% to about 99.8% of a solvent.

8. **(Original)** The transmucosally administrable composition of claim 1, wherein said composition further comprises about 0% to about 50% of a gelling agent.

9. **(Original)** The transmucosally administrable composition of claim 6, wherein the pharmaceutically active compound is a therapeutic compound selected from the group consisting of: IL-2, IL-12, IL-15, IFN- $\alpha$ , IFN- $\beta$ , antivirals, analgesics, pain relievers, antibiotics, peptides, proteins, vitamins, other chemotherapeutic agents, vaccines, and any other

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pharmaceutically active compound that can be efficaciously administered through a transmucosal membrane, and mixtures thereof.

10. **(Original)** The transmucosally administrable composition of claim 1, further comprising an absorption enhancer in a pharmaceutically acceptable form.

11. **(Original)** The transmucosally administrable composition of claim 10, wherein said absorption enhancer is selected from the group consisting of sulphoxides, alcohols, polyols, alkanes, fatty acids, esters, amines, amides, terpenes, surfactants, cyclodextrins, dimethylsulphoxide, pyrrolidones, N,N-diethyl-m-toluamide, and laurocapram.

12. **(Original)** A method of administering a pharmaceutically active compound to the buccal mucosa comprising contacting a composition of claim 1 with a mucosal membrane.

13. **(Original)** The method of claim 12, further contacting the mucosal membrane with an absorption enhancer.

14. **(Original)** The method of claim 13, wherein said absorption enhancer is selected from the group consisting of sulphoxides, alcohols, polyols, alkanes, fatty acids, esters, amines, amides, terpenes, surfactants, cyclodextrins, dimethylsulphoxide, pyrrolidones, N,N-diethyl-m-toluamide, and laurocapram.

15. **(Previously presented)** A method of manufacture of a pharmaceutical composition for administration to the buccal mucosa comprising:

providing a therapeutic compound and a permeation enhancing agent selected from the group consisting of histamine, histamine dihydrochloride, histamine phosphate, histamine agonists, and histamine salts in a pharmaceutically acceptable form, wherein said composition comprises about 0.001% to about 25% weight/volume of said permeation enhancing agent; and

incorporating said therapeutic compound and said permeation enhancing agent into a transmucosal delivery system.

16. **(Original)** The method of manufacture of claim 15, further comprising incorporating into said transdermal delivery system an absorption enhancing agent.

17. **(Original)** The method of claim 16, wherein said absorption enhancing agent is selected from the group consisting of sulphoxides, alcohols, polyols, alkanes, fatty acids,

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esters, amines, amides, terpenes, surfactants, cyclodextrins, dimethylsulphoxide, pyrrolidones, N,N-diethyl-m-toluamide, and laurocapram.